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Original Article

Comparison of Outcomes of Trabeculectomy with Viscoelastic Implant vs. Trabeculectomy with Mitomycin C (MMC)

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ABSTRACT

Objective: To compare trabeculectomy with Mitomycin C (MMC) versus Trabeculectomy with Viscoelastic implant in regards to intraocular pressure (IOP) control, surgical success, and postoperative complications.

Study Design: Quasi-experimental study

Place and Duration of Study: Armed Forces Institute of Ophthalmology (AFIO), Rawalpindi, Pakistan from Apr 2023 to Apr 2024.

Methodology: A total of sixty patients (30 per Group) with Primary Open-Angle Glaucoma (POAG) or Pseudoexfoliation Glaucoma (PXG) fulfilling the inclusion and exclusion criteria were selected. Patients in Group-A underwent trabeculectomy with MMC whereas those in Group-B underwent trabeculectomy with Viscoelastic implant. IOP measurements, bleb morphology, surgical success, and postoperative complications were noted over a 12-month period. Paired and independent t-tests, chi-square tests, and Kaplan-Meier survival analysis were conducted.

Results: At 12 months, mean IOP was comparable between MMC (15.40 ± 2.94 mmHg) and Viscoelastic implant (16.00 ± 3.37 mmHg) ($p = 0.600$). Complete success was attained in 63.3% of Group-A and 43.3% of Group-B ($p = 0.121$), while qualified success was 36.7% and 56.7%, respectively ($p = 0.100$). Postoperative complications were significantly lower in the Group-B ($p = 0.001$). No significant difference was seen in surgical survival ($p = 0.739$).

Conclusion: Both adjuncts effectively reduced IOP, but Viscoelastic implant demonstrated a superior safety profile. It may serve as a safer alternative to MMC, though studies with long-term control are needed to confirm sustained efficacy.

Keywords: Glaucoma, Intraocular Pressure, Mitomycin C, Trabeculectomy, Viscoelastic Agents, Wound Healing.

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INTRODUCTION

Glaucoma is a leading cause of irreversible vision loss, having a 3.8% prevalence in Pakistan and 3.5% worldwide, with patients who have advanced disease and high intraocular pressure (IOP) facing an enormous risk of progression despite prolonged medication, necessitating surgical treatment.[1, 2, 3]

Trabeculectomy remains the gold standard for surgical IOP reduction, with success rates ranging from 55% to 98%.3 Despite its effectiveness, it carries risks of hypotony, choroidal detachment, corneal decompensation, cataract formation, bleb failure and fibrosis.[4]

To improve trabeculectomy outcomes, adjunctive agents like Mitomycin C (MMC) have been used to suppress fibroblast proliferation, thereby enhancing long-term surgical success.[5] However, MMC usage has its own risks including cytotoxicity, leaking blebs, endophthalmitis, choroidal detachment and toxic anterior segment syndrome. [4,6,7]

As an alternative, Viscoelastic implants containing hyaluronic acid (HA) have emerged which modulate wound healing, reduce fibrosis and minimize complications like over-filtration, and hypotony, while maintaining functional blebs.[4] Their anti-inflammatory properties inhibit cytokine activity, improving trabeculectomy outcomes, however, do not affect hyphaema or its clearance.[4,8]

Despite theoretical benefits, the efficacy of sodium hyaluronate-based adjuncts remains unclear. Studies comparing subconjunctival sodium hyaluronate to balanced salt solutions, and those comparing standard trabeculectomy with trabeculectomy with sodium hyaluronate both show no significant difference.[9,10] Additionally research suggests that hypotony prevention may depend more on scleral flap suturing than viscoelastic implant itself.[4] A comparative study by Shalaby et al., found no significant advantage of viscoelastic implants over MMC.[10] Given the risks of MMC, exploring safer

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alternatives like viscoelastic implants is crucial. This study aimed to compare post-operative IOP control, surgical success, and complications between trabeculectomy with MMC and trabeculectomy with viscoelastic implant to determine its viability as an alternative. We hypothesized that trabeculectomy with viscoelastic implant would achieve superior IOP control and success rates while reducing complications compared to MMC.

METHODOLOGY

This quasi-experimental study was executed at the Armed Forces Institute of Ophthalmology (AFIO), Rawalpindi, Pakistan, over a one-year period. Ethical approval was obtained from the Hospital Ethical Review Committee (305/ERC/AFIO, dated 11-04-2023), ensuring adherence to the Declaration of Helsinki.

Inclusion Criteria: Patients who were diagnosed with POAG or PXG, were aged 40–80 years, of either gender, had baseline IOP ≥ 21 mmHg despite maximum medical therapy, and were willing to provide informed consent and follow up for at least 12 months postoperatively were included in the study.

Exclusion Criteria: Patient with a history of previous glaucoma surgery, a history of uveitis or inflammatory eye diseases, angle-closure glaucoma, uncontrolled systemic diseases such as severe diabetes or hypertension, ocular comorbidities affecting IOP measurement (e.g., corneal scarring), or a known hypersensitivity to any study-related medications or materials were included.

Before enrolment, all patients were briefed about the study's purpose, potential risks, and benefits, and written informed consent was obtained. Patient confidentiality was maintained, and data was used solely for research purposes.

Patients undergoing trabeculectomy for primary open-angle glaucoma (POAG) or Pseudoexfoliation Glaucoma (PXG) were recruited. Sample size was calculated using OpenEpi calculator taking power of 80%, margin of error 5%, and mean difference in IOP reduction as 3.24 ± 5.84 mm Hg.[12] The estimated sample size per Group was 26 patients, which was rounded up to 30 per Group to account for potential loss to follow-up, resulting in a total of 60 patients. A convenient sampling technique was used, enrolling all eligible patients who met the criteria during the study period until the target sample size was achieved.

Patients were arbitrarily allocated to either one of the two treatment Groups and the enrollment flow diagram is shown in Figure-1. Initially 85 patients were assessed for enrolment, and 25 were excluded as 15 did not meet inclusion criteria completely and 10 declined to give consent. This left us with 60 patients which were randomly allocated to Group-A or Group-B using simple randomization. A computer-generated random number list was used to assign participants to each Group.

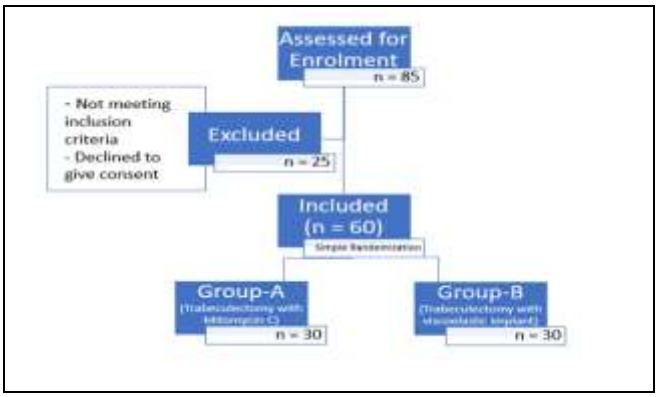

Figure-1: Flow Diagram For Enrollment of Patients (n=60)

In Group-A (trabeculectomy with MMC), MMC was applied intraoperatively to modulate wound healing. In Group-B (trabeculectomy with Viscoelastic implant), a cross-linked viscoelastic gel was injected into the subconjunctival space to prevent excessive fibrosis and maintain a functional bleb.

Baseline data, including age, gender, type of glaucoma, laterality, best-corrected visual acuity (BCVA) using Snellen's chart, glaucoma severity, visual field assessment, baseline IOP (measured using Goldmann applanation tonometry), and the number of anti-glaucoma medications were noted. The diagnosis of advanced glaucoma was based on elevated IOP (>21 mmHg), optic disc changes (severe neuroretinal rim loss in at least three quadrants), and the presence of advanced visual field defects. Intraoperative parameters, such as the date of surgery, surgical technique, and any intraoperative complications were also recorded.

Both Groups underwent standardized trabeculectomy procedures with key differences in adjunctive treatment. All surgeries were executed by the same surgeon under peribulbar anesthesia using a fornix-based conjunctival approach near the limbus. After conjunctival incision, a 4 × 4 mm rectangular scleral flap was dissected in both Groups. In Group-A,

Tenon's capsule was dissection bluntly and conjunctiva was extended between 9 and 3 o'clock to allow additional filtration areas. A 4 × 4 mm sponge soaked in mitomycin C (0.2 mg/mL) was applied under Tenon's capsule and over the intended scleral flap site for 2 minutes, followed by irrigation with balanced salt solution (BSS). A peripheral iridectomy was done following a 1 x 3 mm trabecular block excision. In Group-B, anterior chamber paracentesis was performed, followed by a 1 × 2 mm sclerostomy and a peripheral iridectomy. Viscoelastic implant (0.05–0.1 mL) was injected under the scleral flap, with an additional 0.2–0.4 mL placed between the sclera and conjunctiva to enhance filtration. In both Groups, the scleral flap was secured with two 10-0 nylon sutures, and Tenon's capsule and conjunctiva were closed using 8-0 vicryl sutures. Postoperative management was identical for both Groups. Patients received moxifloxacin 0.5% and prednisolone 0.1% eye drops four times daily for four weeks, with gradual tapering off over 6–8 weeks. Atropine 1% was used three times daily for two weeks.

Postoperative follow-ups were conducted at 1 month, 3 months, 6 months, and 12 months, assessing IOP measurements, IOP reduction, surgical success rates (complete and qualified success), surgical failures, bleb morphology, complication rates (hypotony, bleb leaks, choroidal detachment, fibrosis, infection), and the number of anti-glaucoma medications. Hypotony was defined as IOP ≤6 mmHg, and target IOP was taken as ≤18 mmHg. Complete surgical success was defined as IOP ≤18 mmHg without medication, while qualified success was defined as IOP ≤18 mmHg with medication. Surgical failure was defined as IOP >18 mmHg despite maximum medical therapy, requiring reoperation.

Data analysis was performed using IBM Statistical Package for the Social Sciences (SPSS) Version 25. Continuous variables such as age, IOP values, and IOP reduction were presented as mean ± standard deviation (SD). Categorical variables, such as surgical success rates and postoperative complications, were expressed as frequencies and percentages. Baseline characteristics including age, gender, glaucoma type, and baseline IOP were compared between the two Groups using the independent samples t-test for continuous variables and chi-square test for categorical variables. Paired t-tests were used to compare preoperative and postoperative IOP values, while independent t-tests compared IOP reduction between the two Groups at each follow-up visit. Chi-square tests were used to compare surgical success rates, postoperative complications and bleb morphology between the two Groups. Kaplan-Meier survival analysis was used to compare the 12-month surgical survival rates between the two Groups and a log-rank test was applied to evaluated statistical significance. The *p*-value of ≤ 0.05 was considered statistically significant for all tests.

RESULTS

Sixty patients in total were included in the study, with 30 patients in Group-A (MMC Group) and 30 in the Group-B (Viscoelastic implant Group). The mean age of participants was 61.73 ± 8.9 years and 61.13 ± 8.8 years in Group-A and Group-B, respectively, with no significant difference between the two Groups (p = 0.589). The distribution of gender, glaucoma type (POAG vs. PXG), and baseline intraocular pressure (IOP) were comparable across both Groups (p > 0.05). Table-I summarizes the baseline characteristics of both Groups.

Table-I: Comparison of Baseline Characteristics of Study Participants (n=60)

Variables		Group-A (n=30)	Group-B (n=30)	*p*-value
Age (years)		61.73 ± 8.9	61.13 ± 8.8	0.589
Gender	Female n (%)	10(33.3)	17(56.7)	0.069
	Male n (%)	20(66.7)	13(43.3)	0.069
Glaucoma type	Pseudoexfoliation Glaucoma n (%)	15(50.0)	18(60.0)	0.436
	Primary Open-Angle Glaucoma n (%)	15(50.0)	12(40.0)	0.436
Baseline Intraocular Pressure (mmHg)		26.4±2.2	26.83±2.56	0.488

The mean preoperative IOP in Group-A was 26.4 ± 2.2 mmHg, while in Group-B, it was 26.83 ± 2.56 mmHg, with no significant difference at baseline (p = 0.488). At 1 month, 3 months, 6 months, and 12 months postoperatively, IOP was measured in both Groups. The results are summarized in Table-II.

Table-II: Intraocular Pressure Measurements of Study Participants At Follow-Up Of 1 Month, 3 Months, 6 Months, And 12 Months (n=60)

Point in time	Group-A (Mean ± SD, mmHg) (n=30)	Group-B (Mean ± SD, mmHg) (n=30)	p-value
Baseline	26.40 ± 2.20	26.83 ± 2.56	0.488
1 Month	19.10 ± 3.22	18.93 ± 3.01	0.837
3 Months	17.83 ± 3.36	17.23 ± 2.58	0.600
6 Months	15.80 ± 2.99	16.53 ± 3.34	0.733
12 Months	15.40 ± 2.94	16.00 ± 3.37	0.600

Postoperative IOP reduced significantly in both Groups however it was comparable between them

throughout follow-up. At 12 months, mean IOP reduction in Group-A was 11.00 ± 2.05 mmHg and 10.83 ± 1.93 mmHg in Group-B with a p-value of 0.747 on independent sample t-test, showing no significant difference between the two. IOP at 12 months was also comparable between the two (p = 0.6). Surgical success was classified into Complete Success (IOP ≤18 mmHg without medication), Qualified Success (IOP ≤18 mmHg with medication), and Surgical Failure (IOP >18 mmHg requiring reoperation) whose proportions are summarized in Table-III below. No statistically significant difference was observed in complete and qualified success rates between the Groups (p = 0.121). Even though surgical failure was slightly higher in Viscoelastic implant (20%) vs. MMC (16.7%), but the difference was not statistically significant in this case either (p = 0.739). Table-III summarizes the comparative outcomes between MMC (Group-A) and Viscoelastic Implant (Group-B). While complete and qualified success rates and surgical failure were comparable between the Groups, a significantly higher rate of postoperative complications and differences in bleb morphology were observed (p = 0.001).

Table-III: Comparison of Surgical Outcomes and Complications between MMC (Group-A) and Viscoelastic Implant (Group-B)

Parameter	Group-A Mitomycin C (MMC) (n=30)	Group-B (Viscoelastic Implant) (n=30)	*p*-value
Complete Success	19(63.3%)	13(43.3%)	0.121
Qualified Success	11(36.7%)	17(56.7%)	0.100
Surgical Failure	5(16.7%)	6(20.0%)	0.739
Complications			
Hypotony	9(30.0%)	12(40.0%)	0.001
Bleb leaks	2(6.7%)	0(0.0%)	0.001
Choroidal detachment	7(23.3%)	0(0.0%)	0.001
Bleb Morphology			
Diffuse	9(50.0%)	9(60.0%)	0.001
Flat	0(0.0%)	6(40.0%)	0.001
Encapsulated	9(50.0%)	0(0.0%)	0.001

There was a statistically significant difference between the postoperative complication rates of the two Groups, with a p-value of 0.001. Hypotony was the most commonly reported complication, affecting a total of 19 patients. In Group-B, only mild hypotony was observed in 40% of patients, with significantly fewer complications overall. In contrast, Group-A had a broader range of complications, including hypotony in 30% of patients, bleb leaks in 6.7%, and choroidal detachment in 23.3%.

Bleb morphology also differed significantly between the two Groups (p = 0.001). In Group-B, the diffuse type was the most prevalent, observed in 60% of cases, followed by flat type which was 40% and no cases of encapsulated type were reported. In contrast, in Group-A, the diffuse and encapsulated types were equally prevalent, each accounting for 50% of cases and there were no cases of the flat type. At 12 months, the survival rate for MMC was 83.3% while that for Viscoelastic implant was 80%. The Kaplan-Meier survival curves showed no early drop-offs, indicating the fact that both MMC and Viscoelastic implant maintained high success rates over time, as can be observed in Figure-2. There was no statistically significant difference in survival between the Groups (s = 0.739).

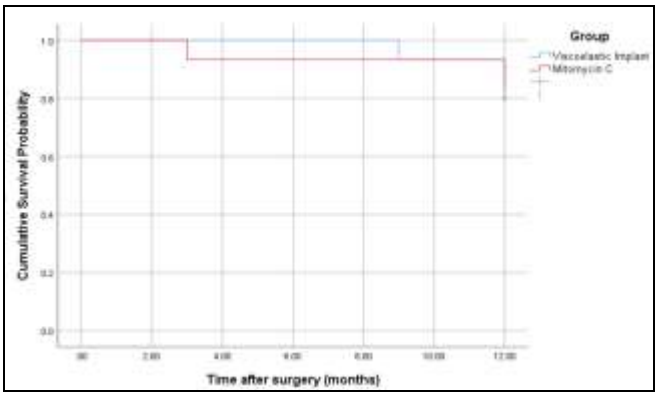

Figure-2: Kaplan–Meier Survival Curves of Surgical Success After Trabeculectomy With Mitomycin C (Mmc) and Viscoelastic Implant

The mean number of anti-glaucoma medications used preoperatively was 3.53 ± 0.507 in Group-A and 3.50 ± 0.51 in Group-B. Postoperatively, the mean number of medications reduced to 1.00 ± 0.83 in Group-A and 0.97 ± 0.85 in Group-B. Paired t-test showed a statistically significant reduction in medication within both Groups with a p-value of <0.001. The mean reduction in medications was 2.17 ± 0.97 in Group-A and 2.53 ± 0.86 in Group-B. The difference between the two Groups was comparable (p = 1.00).

DISCUSSION

The long-term success of trabeculectomy relies on modulation of wound healing, which is achieved by Mitomycin C (MMC), a potent anti-fibrotic agent which decreases proliferation of fibroblasts and excessive scarring. However, its use is associated with complications like hypotony, bleb leaks, and an increased risk of infection.[11] In recent times, another adjunctive therapy, a biodegradable viscoelastic implant, has been introduced as an alternative to MMC, which aims to maintain a functional filtration

pathway whilst also decreasing cytotoxic effects of MMC.[12]

Our study compared the efficacy and safety of trabeculectomy with MMC versus trabeculectomy with Viscoelastic implant in patients with primary open-angle glaucoma (POAG) and pseudoexfoliation glaucoma (PXG), and our findings indicate that both MMC and Viscoelastic implant were effective in significantly lowering IOP postoperatively. At the 12-month follow-up, the mean IOP reduction was comparable between the two Groups (p = 0.6), with an average decrease of approximately 40% from baseline. The number of post-operative medications also reduced amongst both the Groups however there was no significant difference between the two Groups. The postoperative complications were significantly lower in the Viscoelastic implant Group. This aligns with previous research demonstrating that Viscoelastic implant functions as an effective wound modulator, promoting controlled filtration akin to MMC while mitigating its cytotoxic effects.[13]

There has been a mixture of findings seen in Trabeculectomy with MMC and that with Viscoelastic implant. Studies evaluating trabeculectomy with MMC alone have reported a sustained reduction in IOP across follow-up intervals. In one study, the mean number of anti-glaucoma medications reduced from 2.8 ± 0.8 to 0.3 ± 0.7 (p = 0.068), with a complete surgical success rate of 85.7%.[14] Similarly, trabeculectomy with and without Ologen (also a type of viscoelastic implant) demonstrated significant IOP reduction in both Groups (p<0.001), with no statistically significant difference between the two Groups. However, another study comparing trabeculectomy with and without HealaFlow found a significant difference in IOP reduction with HealaFlow.[15] Similarly, in another study, although the MMC Group exhibited a greater initial reduction in IOP on postoperative day 1, but by the 12-month mark, the IOP reduction was comparable between both Groups (46.24% in the HealaFlow Group and 54.47% in the MMC Group, p > 0.05).[16] Additionally, MMC-assisted trabeculectomy has been shown to decrease medication dependence for at least two years postoperatively.[17,18] This was also consistent with the results of our study.

According to the study by Mudhol et al., bleb morphology was similar between the two Groups. 16 However, our study's findings differed in this aspect as bleb morphology was seen to be dissimilar among the two Groups (p=0.001).

Overall, in our study, surgical success which was defined as achieving target IOP without additional medications or surgical interventions was comparable between the MMC and Viscoelastic implant Groups. While the complete success rate was marginally higher in the MMC Group (63.3% as opposed to 43.3%), the difference was not statistically significant. These findings suggest that Viscoelastic implant represents a viable alternative to MMC, particularly for patients at higher risk of MMC-associated complications. Similar outcomes have been reported in previous studies, highlighting Viscoelastic implant's potential in trabeculectomy for long-term IOP control.[19,20]

A key challenge in glaucoma filtration surgery is achieving an optimal balance between efficacy and safety. Although MMC effectively suppresses fibroblast proliferation, it also increases chances of avascular blebs which can leak and cause infections. Previous studies show that there is no significant difference in the complication rates between trabeculectomy alone and trabeculectomy with Viscoelastic implant (p > 0.05) whereas, another study reported a higher frequency of early postoperative complications in the MMC Group (40%) as opposed to the viscoelastic-assisted trabeculectomy (VAT) (21.54%) Group.[15,21] Literature suggests that Viscoelastic implant, by creating a controlled filtration space and gradually resorbing over time, may reduce the risk of excessive scarring without unnecessary fibroblast suppression as seen with MMC.[22,23] Consistent with prior research that demonstrates a lower risk of hypotony and bleb-related complications with Viscoelastic implant, our study also had lower incidence of such complications including bleb leaks, hypotony, and choroidal detachment in the Viscoelastic implant Group. 24, 25

The results of this study have important clinical implications. While MMC remains the gold standard adjunct for trabeculectomy due to its well-established efficacy, Viscoelastic implant itself presents a promising alternative, especially for patients that are at a higher risk of MMC-related complications, such as those with thin conjunctiva, prior ocular surgeries, or a heightened susceptibility to infections. Viscoelastic implant may be a good option in those cases where MMC use is contraindicated or may pose risk of complications.

LIMITATIONS OF STUDY

This study had some constraints, including a relatively smaller sample size and a follow-up duration limited to 12 months. Long-term data is needed to determine whether viscoelastic implant maintains adequate filtration and surgical success beyond one year. Future research should focus on evaluating whether combination strategies (e.g., MMC + Viscoelastic implant) could enhance surgical outcomes. Moreover, comparative studies with other wound modulation techniques may further clarify the role of Viscoelastic implant in glaucoma surgery.

CONCLUSION

Both Mitomycin C and viscoelastic implants effectively lowered intraocular pressure and achieved comparable surgical success after trabeculectomy. However, the viscoelastic implant demonstrated a safer post-operative profile with fewer complications.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

RH & AR: Data acquisition, data analysis, critical review, approval of the final version to be published.

SP & TAK: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SSK & AI: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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